K002880

OCT 2 6 2000

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
8000 Castleway Drive
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Contact Person: Colleen Hittle

Date: August 18, 2000

807.92(a)(2)

Trade Name:	300LC Ultrasound Imaging Systems	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system	892.1550
	Ultrasonic pulsed echo imaging system	892.1560
Classification Number:	90IYN	
	90IYO	

807.92(a)(3)

Predicate Device(s)

Esaote	AU5	K980468

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

K002880

510(k) Summary
300LC
Pie Medical

807.92(a)(5)

Device Description

Intended Use(s)

Pie Medical's 300LC ultrasound system is intended to be used by a physician to perform general diagnostic ultrasound studies including cardiac, peripheral vascular, fetal, abdominal, small organ, neonatal cephalic, transrectal and transvaginal.

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K002880

510(k) Summary
300LC
Pie Medical

Comparison Chart for Substantial Equivalence

General characteristics	**Esaote AU5 (K980468)**	**Pie Medical 300LC**
Transducer type		
Annular Array	yes	no
Mechanical Sector	yes	no
Linear	yes	yes
Convex	yes	yes
Phased array	yes	no
2D Freq MHz	2.5 - 15	2.5 - 10
PW Freq MHz	2.25 - 10	2.5 - 8
CW Freq MHz	2.25 - 5.0	no
Probes MHz		
Annular Array	10 - 20	-
Linear	5.0 - 13	5.0 - 10
Convex	3.5 - 7.5	2.5 - 10
Phased array	2.5 - 3.5	-
Multifrequency probes	yes	yes
Special probes	IVT transvaginal	IVT transvaginal
	TRT transrectal	TRT transrectal
	LP laparoscopic	-
	IOE intraoperative	-
Biopsy attachments		
Convex	yes	yes
Linear	yes	yes
Imaging modes		
Real time 2D	yes	yes
M-mode	yes	yes
PW Doppler	yes	yes
CW Doppler	yes	no
CFM Doppler	yes	yes
Power Doppler	yes	yes
Triplex	yes	yes
Monitor size (inches)	SVGA 15	SVGA 15
Programmability	6 presets	10 presets
Pulsed Doppler	yes	yes
CW Doppler	yes	no
Audio stereo	yes	yes
Color Doppler	yes	yes
ECG	optional	optional
Digital archival capabilities	yes	Yes, optional
VCR	yes	Yes

General characteristics	Esaote AU5 (K980468)	Pie Medical 300LC
M&A capabilities	Fetal, abdominal, intraoperative abdominal, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, peripheral vascular & laparoscopic	Fetal, abdominal, small organ, neonatal cephalic, cardiac, transrectal, transvaginal & peripheral vascular
Safety		
Electrical safety	IEC 60601-1	IEC 60601-1
Ultrasound safety	Track 3 (AOD)	Track 3 (AOD)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2000

Pie Medical
c/o Colleen J. Hittle
Official Correspondent
The Anson Group
8000 Castleway Drive
Indianapolis, IN 46250

Re: K002880
300LC Ultrasound Imaging System
Regulatory Class: II/21 CFR 892.1550 and 21 CFR 892.1560
Product Code: 90 IYN and 90 IYO
Dated: September 15, 2000
Received: September 15, 2000

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 300LC Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number
3.5MHz R40 Convex Array
3.5MHz R60 Convex Array
7.0MHz R10 Convex Array
7.5MHZ L40 Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David A. Seguam

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

300LC

Scanner 300LC

Clinical application	Mode of Operation								
	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal		N	N	N	N	N		X	
Abdominal		N	N	N	N	N		X	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *		N	N	N	N	N		X	
Neonatal Cephalic		N	N	N	N	N		X	
Adult Cephalic									
Cardiac		N	N	N	N	N		X	
Transesophageal									
Transrectal		N	N	N	N	N		X	
Transvaginal		N	N	N	N	N		X	
Transurethral									
Intravascular									
Peripheral Vascular		N	N	N	N	N		X	
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
E=added under Appendix E

Additional comments:
* Small organs include Thyroid, Breast and Testicles

X = Combined mode Duplex and Triplex
Possible modes: B + CD + D / B + AD + D / B + D

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002880

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

300LC

3.5Mhz R40 Convex array

Clinical application	Mode of Operation								
	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal		N	N	N	N	N		X	
Abdominal		N	N	N	N	N		X	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		N	N	N	N	N		X	
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
E=added under Appendix E

Additional comments:
* Small organs include Thyroid, Breast and Testicles

X = Combined mode Duplex and Triplex
Possible modes: B + CD + D / B + AD + D / B + D

David A. Jeppson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002880

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

300LC

3.5Mhz R60 Convex array

	Mode of Operation								
Clinical application	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal		N	N	N	N	N		X	
Abdominal		N	N	N	N	N		X	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		N	N	N	N	N		X	
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
E=added under Appendix E

Additional comments:
* Small organs include Thyroid, Breast and Testicles

X = Combined mode Duplex and Triplex
Possible modes: B + CD + D / B + AD + D / B + D

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002880

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

300LC

7.0Mhz R10 Convex array

	Mode of Operation								
Clinical application	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal		N	N	N	N	N		X	
Transvaginal		N	N	N	N	N		X	
Transurethral									
Intravascular									
Peripheral Vascular									
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
E=added under Appendix E

Additional comments:
* Small organs include Thyroid, Breast and Testicles

X = Combined mode Duplex and Triplex
Possible modes: B + CD + D / B + AD + D / B + D

David A. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003880

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

300LC

7.5Mhz L40 Linear array

	Mode of Operation								
Clinical application	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *		N	N	N	N	N		X	
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		N	N	N	N	N		X	
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
E=added under Appendix E

Additional comments:
* Small organs include Thyroid, Breast and Testicles

X = Combined mode Duplex and Triplex
Possible modes: B + CD + D / B + AD + D / B + D

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